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| 10/790,619 | 03/01/2004 | Gottfried Kellermann | 3942 | 8840 |
| 22474 | 7590 | 02/06/2007 | | |
| CLEMENTS WALKER 1901 ROXBOROUGH ROAD SUITE 300 CHARLOTTE, NC 28211 | | | EXAMINER SASAN, ARADHANA | |
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| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/790,619

Applicant(s)

KELLERMANN, GOTTFRIED

Examiner

Aradhana Sasan

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

1. Claims 1-13 are being presented for examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 7-11 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating headaches and anxiety, does not reasonably provide enablement for any condition or disorder.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The scope of the claims is broad enough to encompass the treatment of any condition or disorder, not just for the treatment of neurotransmitter over-stimulation symptoms such as headache and anxiety.

The specification provides guidance for treating tension headaches, attention deficit disorder, anxiety, and various symptoms associated with neurotransmitter over-stimulation.

Working examples provided are directed toward the alleviation of tension headache and anxiety symptoms (page 11, example 4, page 12, example 5, page 13, example 6). There is only one subject that was treated in each example. The symptoms treated in these examples were headache, stress, anxiety, and inability to relax. Neurotransmitter levels were evaluated after 3 to 8 hours of administration of the theanine composition.

The specification does not teach any specific condition or disorder to be treated other than headache and anxiety symptoms.

The nature of the invention is to treat neurotransmitter over-stimulation symptoms such as headaches, stress and anxiety with theanine and 5-HTP in a liposomal encapsulated oral spray.

The state of the prior art teaches that theanine is similar to the neurotransmitter glutamic acid and reduces blood pressure, and produces a relaxation effect. (Kakuda, 2002, page 1514). Kakuda also teaches that theanine can confer a neuroprotective effect by suppressing glutamate toxicity. The specification of the instant application discloses that theanine modulates the excretion of neurotransmitters like serotonin and dopamine and affects glutamate transport (Specification, page 2). Ueda et al. in US 6,589,566, teach a composition comprising theanine that suppresses and ameliorates symptoms including "anxiogenic symptoms" that are generally associated with

neurotransmitter over-stimulation (Col 1, lines 13-17). However, there is no indication in the art that it could be used to treat other disorders, like diabetes or malaria.

Undue experimentation would be required to use the invention because it is not clear which condition or disorder is going to be treated. In order to treat any condition or disorder with the invention, the quantity of experimentation would be too great.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It would require undue experimentation to use the invention based on the breadth of these claims.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claimed composition includes "an additional therapeutic moiety". It is unclear whether the additional compound is required or modification of the active compound is required.

6. Claims 7-11 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the conditions to be treated by the claimed method. These method claims only disclose "treating a subject" without mentioning any condition or disorder that will be treated.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-6, and 7-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. (US 5,891,465) in view of Ueda et al. (US 6,589,566).

The claimed invention is a composition of a liposomal encapsulated solution containing L-theanine and 5-Hydroxytryptophan. The method of administering the composition is by a spray bottle. Claims 1-6 are drawn to a composition of a liposomal encapsulated solution containing L-theanine and 5-Hydroxytryptophan (5-HTP). Claims 7-11 are drawn to a method of treating a subject using the said composition.

Keller et al. teach compositions and methods of administering drugs or nutritional supplements that are encapsulated in lipid vesicles. The methods of administration include a liquid droplet spray (Abstract). The method of administration by the spray allows the nutritional supplements to be absorbed sublingually (Col 1, lines 10-16). The advantage of sublingual administration is that it "avoids the first pass effect" (Col 2, lines 42-44), provides "increases in the bioavailability and improved therapeutic response..." (Col 3, lines 31-35), and could decrease "the amount of agent that is administered" (Col 4, lines 15-21). "Any form of nutritional supplement that is capable of being entrapped in or bound to the lipid vesicle, can be included..." in the composition (Col 5, lines 3-5). Keller et al. do not teach the use of theanine or 5-HTP in the liposomal encapsulations.

Ueda et al. in US 6,589,566, teach a composition comprising theanine that suppresses and ameliorates symptoms including “anxiogenic symptoms” that are generally associated with neurotransmitter over-stimulation (Col 1, lines 13-17). It is taught that L-theanine is the preferred form of theanine “because it is approved as a food additive, and it is economically utilizable” (Col 3, lines 6-8). The theanine containing composition “may be prepared as ... solutions ...” (Col 6, lines 55-59).

A person with ordinary skill in the art at the time the invention was made would have been able to use the liposomal encapsulated nutritional supplement spray of Keller et al. with the theanine containing solution taught by Ueda et al. given the advantages of sublingual absorption of the liposomal encapsulated spray. One would further have been motivated to use L-theanine and 5-HTP in the liposomal encapsulated composition given the advantage of using these components for the treatment of symptoms caused by neurotransmitter over-stimulation (such as headaches, ADHD, etc.).

As to claims 4 and 5, a person with ordinary skill in the art could, without absent evidence to the contrary, arrive at the optimal concentration range of theanine in the liposomal encapsulated spray solution.

Claim 6 includes “an additional therapeutic moiety”. As mentioned above, Keller et al. teach that any nutritional supplement that can be bound in a lipid vesicle can be included. Therefore, to include an additional therapeutic moiety, which can be bound in a liposome, would be obvious to one with ordinary skill in the art.

Claims 7-11 are inherently met because the composition of Keller et al. is made to be administered to a subject. Therefore, treatment of a subject with nutritional supplements is inherently met.

9. Claims 7-13 rejected under 35 U.S.C. 103(a) as being unpatentable over Blum (US 6,132,724) in view of Keller et al. (US 5,891,465).

Claims 7-11 are drawn to a method of treating a subject and claims 12-13 are drawn to a method of treating a subject with neurotransmitter over-stimulation symptoms such as headaches or attention deficit hyperactivity disorder, by using a liposomal encapsulated solution containing L-theanine and 5-HTP. The method of administering the composition is by a spray bottle.

Blum teaches a method of treating a subject for behaviors that include "attention deficit hyperactivity disorder" (Col 22, line 36-38) by using a composition that includes the neurotransmitter precursor 5-Hydroxytryptophan and Theanine (Col 75, Table 20). "These components promote restoration of normal neurotransmitter functions ..."
(Abstract). Blum does not teach a liposomal encapsulation.

It would have been obvious to make a liposomal encapsulation when Blum is taken in view of Keller et al. because of the teaching of Keller et al. regarding the liposomal encapsulation of nutritional supplements (described in detail in the 103(a) rejection above). A pump spray administration device for the lipid-encapsulated agents is also taught (Col 5, lines 23-27).

A person with ordinary skill in the art at the time the invention was made would have been motivated to combine the method of treatment of restoring normal

neurotransmitter functions by using a composition with theanine and 5-HTP taught by Blum with the liposomal encapsulated nutritional supplement spray of Keller et al. given the advantages of sublingual absorption of the liposomal encapsulated spray.

As to claims 9 and 10, a person with ordinary skill in the art could, without absent evidence to the contrary, arrive at the optimal concentration range of theanine in the liposomal encapsulated spray solution via routine practice of optimization of drug dosage.

Conclusion

1. No claims are allowed.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Friday from 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Andrew Wang or Cecilia Tsang, can be reached at 571-272-8011 and 571-272-0562 respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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